



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Thursday, March 30, 2006

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 74771-G/
Benefect Botanical Daily Cleaner Disinfectant
DP Barcode: D325394

To: Adam Heyward, PM 34/ Renae Whitaker
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *ILB*
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Through: Karen Hicks, Team Leader
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Applicant: Sensible Life Products (Division of LBD Ltd.)

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Thymol (present as a component of Thyme Oil)	0.05
<u>Other Ingredient(s):</u>	<u>99.95</u>
Total:	100.00%

1) BACKGROUND: Sensible Life Products, Inc., asks for waivers of the acute toxicity battery of studies for its product, "Benefect Botanical Daily Cleaner Disinfectant". The MRID Number is 467246-03. Actually, this submission is more like a request to cite public literature and other available data sources (M.S.D.S.s) to support the acute toxicity requirements of this product. The rationales for this waiver/citation are:

- a) The product consists of [REDACTED].
- b) The active ingredient, thymol, is found in the product at a concentration of 0.05%.
- c) Three or more of the other ingredients are on the FDA's Generally Recognized As Safe (GRAS) list.
- d) The MSDSs of each of the product's ingredients are included in the report.

2) RECOMMENDATIONS: PSB findings are:

- a) CTT/PSB denies the citations of the primary eye irritation and acute inhalation toxicity studies. The reasons for these denials are:
 - i) Eye irritation study: Some of the ingredients (even found in low concentrations) in this product are irritants.
 - ii) Acute inhalation toxicity study: Some of the ingredients in this product are aromatics and are known to cause respiratory irritation.

The registrant must submit primary eye irritation and acute inhalation toxicity studies for this product, or, find some better means of data support.

b) CTT/PSB will allow the data citations of the following studies:

- i) Acute oral toxicity
- ii) Acute dermal toxicity
- iii) Primary skin Irritation
- iv) Dermal sensitization.

The low concentrations of the ingredients found in this product are not expected to cause oral toxicity, dermal toxicity, skin irritation or dermal sensitization. The registrant does not have to conduct acute toxicity studies for these four data requirements.

Note: These decisions were made with the assistance of three RASSB Ph.D. toxicologists.

The acute toxicity profile for File Symbol 74771-G is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	467246-03	IV	Cited
Acute Dermal Toxicity	467246-03	IV	Cited
Acute Inhalation Toxicity	467246-03	Data Requested	Data Gap
Primary Eye Irritation	467246-03	Data Requested	Data Gap
Primary Skin Irritation	467246-03	IV	Cited
Dermal Sensitization	467246-03	IV	Cited

3) LABELING:

- a) CTT/PSB cannot recommend precautionary labeling at this time.